



**Health Plan Benefits Group/CBC**

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**DATE:** November 25, 2003

**TO:** Medicare +Choice Organizations  
Medicare Cost Plans  
Medicare +Choice Demonstrations

**FROM:** Cynthia Moreno /s/  
Acting Director

**SUBJECT:** Establishment of National File & Use Marketing Program

I am pleased to provide you with the opportunity to take advantage of an innovative improvement to the marketing review process. In particular, beginning January 1, 2004, CMS is implementing a national File & Use program.

The File & Use program is designed to streamline the marketing review process. Under this process, Medicare +Choice (M+C) organizations, demonstrations, and Medicare Cost plans that can demonstrate to CMS that they can continually meet a particular standard of performance will be able to publish and distribute certain marketing materials without prior CMS approval. The File & Use program has several advantages. It can not only decrease the time it takes for an organization to begin using certain marketing materials, but can also help organizations schedule their publication of advertising materials.

Some organizations are already following a "Use & File" process with their Regional Office. These organizations do not need to take steps to "re-qualify" for File & Use. However, please refer to the attached File & Use instructions, as they differ from the process you are currently using. Beginning January 1, 2004, you must use the attached File & Use instructions in order to continue with the File & Use program. You may not continue to use the "Use & File" process you were using previously.

Beginning January 1, 2004, any organizations not currently participating in the "Use & File" pilot project may begin requesting to go on File & Use status. Requests to go on File & Use status must be made to the Regional Office, in writing.

To ensure that all your questions regarding the new File & Use program are addressed, we have designated a National File & Use Coordinator in the CMS Central Office. This Coordinator, along with the National Marketing Product Consistency Team (PCT), which consists of staff in every Regional Office, will address issues regarding interpretation of File & Use requirements. You may send any questions you have either to the National File & Use Coordinator or to your Regional Office Contact or Marketing Review Specialist, who will ensure that the Coordinator

and the PCT responds to you. The National File & Use Coordinator is Anne Avery, who can be reached at 410-786-6557 or [aavery@cms.hhs.gov](mailto:aavery@cms.hhs.gov).

We will update Chapter 3 of the Medicare Managed Care Manual to include this new process.  
Thank you.

Attachment

## Attachment

### File & Use Policies and Procedures

Either the parent company (which could be a multi-site organization but is not always a multi-site organization) or the contracting entity can request that the Regional Office grant File & Use status to the contracting entity. File & Use status is given to and maintained by a contracting entity (i.e., also known as the “organization,” this is the entity that is granted a single H #). All plans (PBPs) within a single H # will be a part of the File & Use program once the single H # is on File & Use status. Individual contracting entities can maintain this status even if other entities in the parent company do not. For example, if a parent company operates in a number of different States (i.e., has several different H #s), and File & Use status is given to only a subsidiary operating in one State, that subsidiary organization may maintain its File & Use status, even if the subsidiaries in other States do not.

The CMS region that is the lead for that multi-region company maintains File & Use status for multi-region companies. If File & Use status is granted to a multi-region company, it means that the lead Regional Office (i.e., the “multi-region team lead”) has granted File & Use privileges to all national materials developed by the multi-region company. The local Regional Office must still review local materials, unless the local contracting entity has been granted File & Use status by the local Regional Office.

Some organizations use many non-English marketing materials. Once a contracting entity is granted File & Use status, both the English and non-English materials are included within the File & Use program.

#### Definitions

**Eligible Material:** All advertising and pre-enrollment materials used to market the health plan to potential enrollees through a format of general circulation, all enrollment and disenrollment letters, and any post-enrollment materials that do not describe benefits and/or cost sharing and/or plan rules (see below).

Materials that are **not** eligible for the File & Use program are materials that CMS believes pose greater risk to a Medicare beneficiary if they are inaccurate in any way. These are post-enrollment materials (beneficiary notification materials) that describe benefits and/or cost sharing and/or plan rules and enrollment and disenrollment forms. These include materials such as the Evidence of Coverage, Summary of Benefits, and other member notices (such as the Annual Notice of Change, provider termination notices, claims denial notices, etc.).

**Acceptable:** All material that is not materially inaccurate or misleading or otherwise makes a material misrepresentation, which means that the material follows the guidelines delineated in Chapter 3 of the Medicare Managed Care Manual. It also means that, as submitted, the materials do not need to be changed to avoid adverse impact on a beneficiary’s decision to elect the

plan or to disenroll and/or to avoid leading a member to believe that he/she could not get coverage for a covered service.

Examples of changes that would result in a material being unacceptable include failing to include a disclaimer that a particular benefit is not available to everyone or providing inaccurate premium or benefit information.

Example of changes that would not cause a material to be unacceptable (i.e., it would still be “acceptable”) might be to not adhere to font-size requirements for an ad or to provide incorrect dates or times for a sales presentation. Keep in mind that persistent errors in sales presentation dates or persistent failure to adhere to font size requirements could cause CMS to begin considering an organization’s materials to be unacceptable.

### **Eligibility for the File & Use Program**

Since monitoring of the File & Use program is conducted on a quarterly basis, an organization may only begin File & Use status at the beginning of a calendar quarter (i.e., January 1, April 1, July 1, or October 1). However, we will grant a one-time exception to these time frames with the launch of this nationwide program and allow an organization to request File & Use status to begin at any time between January 1 and April 1, 2004. After April 1, 2004, File & Use status is once again only granted on a calendar quarter basis.

Organizations that use the File & Use program are agreeing to retract and revise any materials that are later determined by CMS to be misleading or inaccurate, or do not follow the guidelines outlined in Chapter 3 of the Medicare Managed Care Manual.

To become eligible for or to stay on the File & Use program, an organization must meet the following criteria.

#### **How to Attain File & Use Status**

Beginning January 1, 2004, any organization may request to be on File & Use. To attain File & Use status:

1. The organization must request in writing to the Regional Office to be on File & Use.
2. The CMS Regional Office will select a random sample of eligible materials that the organization submitted to the Region for review over the prior 6 months. Ninety (90) percent of these materials must be “acceptable,” according to File & Use criteria. This means that while the materials were pre-approved by the Regional Office, they would have met the definition of “acceptable” even if the Regional Office had not reviewed them.
3. The contracting entity (i.e., the H#) must have been in the M+C/Medicare Cost plan program for at least the last 18 months. One exception to this 18-month rule is if the parent company has been in the program for over 18 months and the parent company

requests that the contracting entity be given File & Use status even though the H# has not been in the program for 18 months.

4. The CMS Regional Office Branch Chief will notify the organization of the Region's decision in writing. The Regional Office will make every effort to try and provide notification within one month of the organization's request to be on File & Use.
5. If the organization disagrees with the Regional Office's decision, it can notify the National File & Use Coordinator of its disagreement. The National File & Use Coordinator and the Marketing PCT will review the decision made by the Regional Office and notify the organization in writing if the decision is upheld or overturned.

#### How to **Maintain** File & Use Status

Once an organization is on the File & Use program, it must do the following to maintain that status:

1. Ninety (90) percent of eligible materials used under the File & Use program during the preceding calendar quarter must be "Acceptable" per File & Use criteria (as determined by the Regional Office). The Regional Office will conduct quarterly reviews of random sample of materials filed under the File & Use program to determine whether the materials meet this performance standard. In markets where foreign language marketing materials are used, the CMS Regional Office may select such pieces in the sample that will be reviewed.
2. The organization must follow the procedures outlined in the section below entitled "Procedures to Follow When using File & Use."
3. The organization must continue to submit to CMS materials that are not eligible for the File & Use program in accordance with the requirements outlined in Chapter 3 of the Medicare Managed Care Manual. (For clarification, see the definition of "Eligible Material" above.)

#### **Procedures to Follow When using File & Use**

1. The organization must provide CMS with copies of all final materials within **5 calendar days prior** to their distribution. "Final" materials are the copies that will be sent to the printer, or the comparable copies that are provided for reproduction.
  - All organizations must specify the expected date of initial distribution or publication when filing materials with CMS.
  - All organizations must clearly indicate on the front cover of the Marketing Material Transmittal sheet that the material is being filed as a "File & Use" material. Note: The Marketing Material Transmittal Sheet will be updated shortly to include a box in the "Type of Review" section to check off "File & Use." Meanwhile, please just write "File & Use" directly onto the transmittal sheet.

- Upon receipt of the materials, CMS will log them into the Marketing Module of the Health Plan Management System.
2. Organizations that have File & Use privileges may still submit for prior approval any eligible materials with respect to which they would like guidance from CMS. This may prevent an organization from losing File & Use privileges.
  3. If the organization submits materials under the File & Use program but later decides it does not want to use the materials, it must notify the Regional Office in writing that it no longer intends to use them. This is to ensure that the Regional Office does not review those materials as part of the random sample reviewed during the quarterly review.

### **Loss of File & Use Status**

An organization may lose File & Use status if it:

- uses materials that do not meet the definition of “Acceptable” and/or,
- fails to file two or more materials at least 5 calendar days prior to distribution or publication.

The Regional Office will notify the organization in writing if it is in danger of losing File & Use status. This notice will indicate that the organization has been placed on a probationary review period and will delineate the length of the probationary period. The length of the probationary period will be determined by the Regional Office on a case-by-case basis, depending on the type and impact of errors identified in marketing materials, but generally will last no less than one month and no more than one calendar quarter in length.

During the probationary period, the Regional Office will conduct an increased level of spot checks of marketing materials used under the File & Use process. In the middle of the probationary period, the Regional Office will provide written notice to the organization indicating whether it has seen improvement during the spot checks of marketing materials, or if the organization is still in danger of losing File & Use status. At the end of the probationary period, the Regional Office will notify the organization in writing regarding whether or not the organization may continue with File & Use status. If the determination is to terminate File & Use status, this notice will provide the organization with 10-day advance notice of the termination.

Termination of File & Use status does not mean that an organization may never again obtain File & Use status. If CMS terminates an organization’s File & Use status, the organization may request to get back on File & Use once at least two calendar quarters have passed since its status was terminated. If an organization loses File & Use status twice, it may not request to get back on File & Use status for at least one year after the status was terminated the second time.